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PATENT

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AUG 23 2002

Applicant : Schneewind et al.  
 Appl. No. : 09/292,437  
 Filed : April 15, 1999  
 For : IDENTIFICATION OF  
 SORTASE GENE  
 Examiner : Navarro, Albert Mark

) Group Art Unit 1645

TECH CENTER 1600/2900

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 8/26/02

PETITION FROM REQUIREMENT FOR RESTRICTION UNDER  
37 C.F.R. § 1.144

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PETITIONS OFFICE

Dear Sir:

In connection with the above-identified patent application a restriction requirement was issued in an Office Action mailed on October 4, 2000 (Paper No. 12). Applicants were requested to elect, for examination purposes, one of the inventions listed as Groups I - XIII, and, if electing Group XII or Group XIII, further restrict the claims to one of SEQ ID NOs: 4, 5, 6, 7, 8, 35, or 36.

In a Response to Restriction Requirement dated December 4, 2000, applicants elected the invention of Group II (claims 8-25) with traverse, and advanced arguments as to why the restriction requirement was improper and should be withdrawn.

In an Office Action mailed on March 14, 2001 (Paper No. 16, the "Second Restriction Requirement"), the Examiner repeated the earlier Restriction Requirement, acknowledged Applicants' election of Group II, with traverse, and added the further requirement of restricting

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Appl. No. : 09/292,437  
Filed : April 15, 1999

one of the nucleic acid species encompassed by claim 8, e.g. nucleic acid encoding a protein of SEQ ID NO: 3, or another single nucleotide sequence encoding a single protein within the scope of claim 8. The Office Action cites MPEP 803.04.

In a Response to Second Restriction Requirement dated May 17, 2001, Applicants repeated the election of Group I, claims 8-25, and the nucleotide sequence encoding the protein of SEQ ID NO: 3, with traverse, and in addition to the earlier arguments, specifically argued why the requirement for electing a single nucleic acid species that encodes only a single protein sequence of SEQ ID NO: 3, or a variant thereof should be withdrawn.

In an Office Action mailed on July 23, 2001 (Paper No. 19, herein referred to as the Final Restriction), the Examiner acknowledged Applicants' election of Group II, claims 8-25, and nucleic acid sequences encoding the protein of SEQ ID NO: 3, with traverse, repeated the earlier arguments why the restriction between Groups I-XIII was proper, and made the restriction final. The Examiner gave no reasons whatsoever why, in the case of electing Group II, the requirement to restrict the application to nucleic acid encoding a single polypeptide within the scope of claim 8 was also proper. Indeed, the Final Restriction clearly indicated that while claims 1-7 and 26-97 were withdrawn from consideration, claims 8-25 remained pending for examination on the merits.

In an Amendment and Response to Office Action dated January 22, 2002, applicants cancelled claims 11-13, 17, 21, and 25, amended claims 8-10, but maintained their earlier position that the requirement to limit the nucleotide sequences encompassed by claim 8 to a single species was improper, and specifically reserved the right to petition to the Commissioner to review the requirement, as provided in 37 C.F.R. § 1.144.

APPLICANTS HEREBY PETITION and request the withdrawal of the requirement to restrict the application to a single species of nucleic acid encoding a single species of protein within the scope of claim 8.

Appl. No. : 09/292,437  
Filed : April 15, 1999

THE PRESENT PETITION IS FILED AFTER THE RESTRICTION REQUIREMENT WAS MADE FINAL, AND NOT LATER THAN THE FILING OF AN APPEAL. Accordingly, the present Petition is in full compliance with 37 C.F.R. § 1.144.

GROUND FOR THE PETITION:

1. *The Final Restriction should be read to include nucleic acid encoding variants of SEQ ID NO: 3*

According to the Final Restriction (July 23, 2001), claims 1-7 and 26-97 were withdrawn from consideration, and claims 8-25 remained for examination on the merits. Claims 8 and 9 both relate to an isolated nucleic acid molecule encoding a sortase transamidase enzyme from a Gram-positive bacterium. In claim 8, the enzyme comprises the amino acid sequence of SEQ ID NO: 3 and variants of the amino acid sequence of SEQ ID NO: 3 having one or more specified conservative amino acid substitutions. The Final Restriction, clearly states that the claims under examination in the present application include claims 8 and 9. The Final Restriction does not state that the subject matter of claim 8 is limited to SEQ ID NO.3, and does not provide any reasons why, despite applicants' traversal, the limitation of claim 8 to nucleic acid encoding SEQ ID NO: 3 (or to any other nucleotide sequence encoding a single protein) would be proper. Indeed, had the Examiner in effect restricted claim 8 to a nucleic acid encoding a sortase transamidase enzyme comprising the amino acid of SEQ ID NO 3, claim 8 would have become duplicative of claim 9. It is not reasonable to expect that that claim 8 would remain pending if the examination would only include the subject matter of claim 9.

For all the reasons discussed above, the only reasonable reading of the Final Restriction leads to the conclusion that examination was restricted to the invention of Group II, without an additional restriction to the nucleic acid encoding SEQ ID NO: 3. This conclusion is further supported by the noted fact that, although Applicants presented plausible arguments against the narrow restriction, a clear supported rebuttal was not provided. The absence of an Examiner's reply (to Applicants' arguments advanced in traversing the requirement to restrict the application to a single nucleic acid species encoding a single species of protein within the scope of claim 8) is contrary to the provisions of M.P.E.P. 821.01.

Appl. No. : 09/292,437  
Filed : April 15, 1999

2. The restriction does not properly apply MPEP 803.04

Restriction practice for nucleotide sequences encoding proteins under MPEP 803.04 relates to proteins that are unrelated. In this case the nucleic acids of claims 8 and 9 all encode a sortase transamidase from a Gram-positive bacterium. Accordingly, the all sequences within the scope of claim 8, and the sequences of claims 8 and 9 are functionally related. The differences between the claim 8 and 9 sequences are conservative amino acid substitutions, therefore, the sequences are structurally closely related. Since the nucleic acid sequences encompassed by claim 8 are both structurally and functionally related, M.P.E.P. 803.04 does not apply.

3. The restriction is not proper under MPEP 803.

Under MPEP 803, the Examiner must examine the application on the merits if the search and examination of an entire application can be made without a serious burden, even though the application includes claims to independent or distinct inventions. Searching for nucleotide sequences encoding SEQ ID NO:3 and the specified conservative amino acid substitution variants of SEQ ID NO: 3 would not place an undue burden on the Examiner. Following the claim language, in addition to nucleic acid encoding the polypeptide of SEQ ID NO: 3, the following variants need to be searched:

- (1) variants of SEQ ID NO: 3 in which any of isoleucine, leucine, and valine is replaced by any other of these amino acids;
- (2) variants of SEQ ID NO: 3 in which aspartic acid is replaced by glutamic acid, or glutamic acid is replaced by aspartic acid;
- (3) variants of SEQ ID NO: 3 in which glutamine is replaced by aspartic acid, or aspartic acid is replaced by glutamine; and finally,
- (4) variants of SEQ ID NO: 3 in which serine is replaced by threonine or threonine is replaced by serine.

It is straightforward and easy to design a routine electronic search request, where the indicated amino acids are included as variables, following the directions of the claim language. Accordingly, it would not be undue burden on the Examiner to conduct a sequence identity search within the full scope of claim 8.

Since there are no supported arguments to validate the alleged burdensome search, the restriction is not proper, and claim 8, in its entirety, should be examined on its merits.

Appl. No. : 09/292,437  
Filed : April 15, 1999

4. While the search within the full scope of claim 8 would not place undue burden on the Examiner, a heavy burden is placed on Applicants

If Applicants were to be forced to pursue every single species encompassed by claim 8 in a separate patent application, the burden would be overwhelming. It is easy to see that the filing of individual patent applications for each individual species would be cost-prohibitive on virtually any budget. Accordingly, such requirement, if maintained, would deprive Applicants of the benefit of their invention, would open up avenues for others to easily circumvent Applicants' invention relying on Applicants' own teaching in the disclosure of the present application. Such outcome would be contrary to public policy, contradicting basic principles of patent law, and should not stand.

5. The Examiner's Final Restriction is not supported by MPEP 803.04

The Commissioner has decided to permit the examination of a reasonable number of nucleotide sequences in a single application (Examination of Patent Application Containing Nucleotide Sequences, 1192 O.G. 68 (November 19, 1996; M.P.E.P. 803.04). Applicants submit that the number of closely related nucleic acid sequences encompassed by original claim 8 is reasonable. Therefore, such sequences should be examined in a single application.

6. MPEP 706.03 (k) is not a proper rejection for claims 8 and 9 since the literal claim scope is clearly not duplicative

It is noted that MPEP 706.03 (k) relates claims that are duplicative in content. Clearly claims 8 and 9 are not duplicates in scope for the reasons outlined above. MPEP 706.03 does not provide for duplicates based on a construction of pending claims in view of a restriction.

In conclusion, based on the foregoing arguments, Applicants hereby request the withdrawal of the restriction requirement requesting the restriction of claim 8 to a single nucleic acid species encoding a single polypeptide.

A favorable consideration of the present Petition is respectfully requested.

Appl. No. : 09/292,437  
Filed : April 15, 1999

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: August 20, 2002

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